

## **REMARKS**

### ***In the Specification***

Applicant amended the specification to correct a typographical error.

### ***In the Claims***

Applicant voluntarily amended claims 28, 30, 31, 35, 36, 38, and 40, to more clearly define the claimed invention. Applicant voluntarily cancelled claims 29 and 33. Applicant also added new claims 44-46. The amended and new claims are supported by the originally filed specification and do not introduce any new matter.

### ***Claim Rejections – Double Patenting***

Claims 28 and 35 were rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claim 6 of U.S. Pat. No. 6,715,485 (the '485 patent). Applicant traverses this ground for rejection.

Applicant voluntarily amended claim 28 to recite the structural element of “an exogenous gas supply unit for supplying a gas flow into the nasal airway of the subject and configured to provide an alternating pressure in the nasal airway of the subject during the exhalation breath.” Claim 6 of the '485 patent does not include this structural element and is not capable of performing the required function. Therefore, amended claim 28 is patentably distinct from claim 6 of the '485 patent.

Applicant voluntarily amended claim 35 to recite the structural element of “an exogenous gas supply unit for alternately delivering and withdrawing a volume of gas through the nasal airway of the subject during the exhalation breath, such as to cause entrained substance to be flushed in alternate directions therethrough.” Claim 6 of the '485 patent does not include this structural element and is not capable of performing the required function. Therefore, amended claim 35 is patentably distinct from claim 6 of the '485 patent.

Accordingly, Applicant respectfully requests that the double patenting rejections be reconsidered and withdrawn.

***Claim Rejections – 35 U.S.C. § 103***

Claims 1, 3-16, 18-31, 33, 35, 36, 38-41, and 43 were rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Djupesland '672 (WO 00/51672), in view of Djupesland '689 (WO 01/97689), and further in view of Alving (US 6,019,100). Applicant traverses this ground for rejection and respectfully requests that the Examiner reconsider and withdraw it.

***Claims 1, 3-16, and 18-27***

The Examiner alleged that Djupesland '689 (Figures 5A to 5D) discloses a collection reservoir (330), which the Examiner presented as the claimed substance supply unit, first and second nasal olives (311, 312), which the Examiner presented as the claimed first and second nosepiece units (311, 312), and a three-way valve (335), which the Examiner presented as the claimed valve unit. See the Office Action mailed 07/21/2009 at page 3.

As Applicant discussed in the Response dated 04/28/2009, the collection reservoir (330) is merely a conduit through which the exhaled air flow is directed to the nasal airway and is not configured to supply a metered dose of substance in the manner claimed by Applicant. Accordingly, the Djupesland '689 does not disclose or suggest a substance supply unit as in Applicant's claims.

Further, contrary to the Examiner's allegation, the three-way valve (335) of Djupesland '689 does not fluidly connect the collection reservoir (330) to one of the nasal olives (311, 312), in the manner claimed by Applicant. As stated expressly at page 17, lines 28 to 32 and illustrated in Figure 5B of Djupesland '689, the three-way valve (335) is fluidly connected to the inlet of the collection reservoir (330). In being fluidly connected to the inlet of the collection reservoir (330), the three-way valve (335) does not and cannot provide a fluid connection between the collection reservoir (330) and either of the nasal olives (311, 312). It is a very different device in both structure and function.

The Examiner acknowledges that the Djupesland '672 and '689 references lack a valve unit for selectively fluidly connecting a substance supply unit (for supplying a metered dose of substance) alternately to respective nosepiece units. Apparently, the Examiner would find this feature in Alving. See the Office Action mailed 07/21/2009 at

page 3. However, this is not the case. Alving expressly teaches only the flushing and removal of gas from the upper airways (e.g., taking NO from the nasal cavity) and delivering that gas to the lower airways (e.g., the lungs, in ventilator-assisted breathing). Alving does not teach or suggest anything resembling “selectively deliver[ing] medicament to either nosepiece ....” *Id.*

In summary, the devices described in Djupesland ‘689 and Alving are so different in structure, function and purpose that they cannot readily be combined with Djupesland ‘672 to yield anything approaching the claimed invention. Furthermore, the alleged three-way combination lacks altogether a valve unit, as described in Applicant’s independent claim 1, and the step of delivering a metered dose of substance alternately through respective nosepiece units, as described in Applicant’s independent claim 16. It is respectfully submitted that the subject matter of claims 1 and 16 is patentably distinguished over Djupesland ‘672, in view of Djupesland ‘689, and further in view of Alving.

Claims 28-31 and 33

Applicant voluntarily amended claim 28 to require an exogenous gas supply unit for supplying a gas flow into the nasal airway of the subject and configured to provide an alternating pressure in the nasal airway of the subject during the exhalation breath and voluntarily amended claim 31 to require supplying an exogenous gas flow having an alternating pressure into the nasal airway of the subject during the exhalation breath.

In connection with claim 28, the Examiner alleged that Alving’s pump units (3A, 3B) provide for cycling of the pressure in the nasal airway. See the Office Action mailed 07/21/2009 at page 8.

However, with respect to amended claim 28, Alving does not teach or suggest an exogenous gas supply unit for supplying a gas flow into the nasal airway of the subject and configured to provide an alternating pressure in the nasal airway of the subject during the exhalation breath. Rather, Alving’s pump units (3A, 3B) are limited to alternation after a complete breathing cycle (e.g., both inhalation and exhalation). Alving does not and cannot function to provide an alternating pressure in the nasal airway of the subject during the exhalation breath.

In connection with claim 31, the Examiner alleged that Djupesland '689 discloses that the exhalation of the subject will inherently vary during the breathing cycle. See the Office Action mailed 07/21/2009 at pages 8 and 9.

However, with respect to amended claim 31, Alving does not teach or suggest supplying an exogenous gas flow having an alternating pressure into the nasal airway of the subject during the exhalation breath. An exogenous gas flow is not an exhalation gas flow. Therefore, the Examiner's argument no longer applies in view of the claim amendments.

In summary, it is submitted that the subject-matter of claims 28 and 31 is patentably distinguished over the cited art. The rejection of claims 29 and 33 is now moot in view of the voluntary cancellation of these claims.

Claims 35 and 36

Applicant voluntarily amended claim 35 to require an exogenous gas supply unit for alternately delivering and withdrawing a volume of gas through the nasal airway of the subject during the exhalation breath, such as to cause entrained substance to be flushed in alternate directions therethrough and voluntarily amended claim 36 to require alternately delivering and withdrawing a volume of exogenous gas through the nasal airway of the subject during the exhalation breath such as to cause the substance to be flushed in alternate directions therethrough.

In connection with claims 35 and 36, the Examiner alleged that Alving's pump units (3A, 3B) can alternately deliver and withdraw a volume of gas. See the Office Action mailed 07/21/2009 at page 9.

However, with respect to amended claims 35 and 36, Alving does not teach or suggest alternately delivering and withdrawing a volume of gas through the nasal airway of the subject during the exhalation breath. Rather, Alving's pump units (3A, 3B) are limited to alternation after a complete breathing cycle (e.g., both inhalation and exhalation). Alving does not and cannot function to alternately deliver and withdraw a volume of gas through the nasal airway of the subject during the exhalation breath.

In summary, it is submitted that the subject-matter of claims 35 and 36 is patentably distinguished over the cited art.

Claims 38-41 and 43

The Examiner alleged that claim 38 is obvious in view of Djupesland '672. This is not the case.

Applicant voluntarily amended claim 38 to clarify the claimed invention. Claim 38 now recites a cavity being closed off by a flexible member which is deflectable on exhalation into the mouthpiece so as to trigger a substance supply unit in the nasal delivery device.

The Examiner alleged that Djupesland '672 discloses a flow resistor (28) that can be a biased flap (at page 17, last line to page 18, line 2), and that this biased flap provides Applicant's closed flexible member. See the Office Action mailed 07/21/2009 at page 10. This is not the case. Djupesland '672 discloses that the tubular section (24) requires a flow therethrough (page 17, lines 27 and 28), and such a flow is incompatible with a cavity being closed off by a flexible member, as required by amended claim 38.

In summary, it is submitted that the subject-matter of claim 38 is patentably distinguished over the cited art.

Dependent Claims

It is submitted that the dependent claims are allowable as depending upon allowable independent claims.

**CONCLUSION**

For at least the foregoing reasons, Applicant respectfully submits that all of the pending claims are in condition for allowance and requests early favorable action. If the Examiner believes a telephonic interview would expedite the prosecution of the present application, the Examiner is welcome to contact Applicant's representatives at the number below.

Respectfully submitted,

Date: April 29, 2010

/Isaac A. Hubner, Reg. No. 61,393/  
Isaac A. Hubner, Reg. No. 61,393  
Agent for the Applicant  
Proskauer Rose LLP  
One International Place  
Boston, MA 02110  
Tel. No.: (617) 526-9893  
ihubner@proskauer.com

/Kristin H. Neuman, Reg. No. 35,530/  
Kristin H. Neuman, Reg. No. 35,530  
Attorney for the Applicant  
Proskauer Rose LLP  
1585 Broadway  
New York, NY 10036-8299  
Tel. No.: (212) 969-3385  
kneuman@proskauer.com